



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/565,185 | 04/10/2006 | Peter Ellinghaus | Le A 36 823 | 5232 |
| 35969 | 7590 | 10/02/2009 | EXAMINER | |
| Barbara A. Shimek | | | BUNNER, BRIDGET E | |
| Director, Patents & Licensing | | | ART UNIT | PAPER NUMBER |
| Bayer HealthCare LLC - Pharmaceuticals | | | | 1647 |
| 555 White Plains Road, Third Floor | | | | |
| Tarrytown, NY 10591 | | | | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 10/02/2009 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/565,185 | ELLINGHAUS ET AL. | |
| | Examiner | Art Unit | |
| | Bridget E. Bunner | 1647 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 24 July 2009.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-3 and 5 is/are pending in the application.
 4a) Of the above claim(s) 1,3 and 5 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 2 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) 1-3 and 5 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 18 January 2006 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

The Art Unit location and the examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Bridget E. Bunner, Group Art Unit 1647.

Status of Application, Amendments and/or Claims

The amendment of 18 January 2006 has been entered in full. Claims 1 and 5 are amended. Claim 4 is cancelled.

Election/Restrictions

Applicant's election with traverse of Group II, claim 2, directed to a method for screening compounds in the reply filed on 24 July 2009 is acknowledged. The traversal is on the ground(s) that each of the claims of Groups I through IV are linked so as to form a single general inventive concept; namely, methods for identifying and using modulators of a particular set of potassium channels TWIK-1, TASK-1, GIRK1, SK2, or PCN1, which were identified it is believed for the first time as being differentially expressed in the atrium as compared to in the ventricle of the human heart. Applicant argues that since the Groups are linked by the above "special technical features" as required under PCT Rule 13.2, a restriction should not be proper. This is not found persuasive. As discussed at pages 3-4 of the previous Office Action of 24 March 2009, Groups I-IV lack unity of invention because even though the inventions of these groups require the technical feature of modulators of the potassium channels TWIK-1, TASK-1, GIRK1, SK2, or PCN1, this technical feature is not a special technical feature as it does not make a contribution over the prior art of Curtis et al. (US20020028483) or Jansen et al. (U.S. Patent 6,194,447).

Applicant's election with traverse of the species of a modulator of TWIK-1 in the reply filed on 24 July 2009 is acknowledged. The traversal is on the ground(s) that each of the species

of modulators of TWIK-1, TASK-1, GIRK1, SK2, or PCN1 are so linked as to form a single general inventive concept; namely, potassium channel proteins that are differentially expressed in the atrium as compared to in the ventricle of the human heart. Applicant argues that since the Groups are linked by the above "special technical features" as required under PCT Rule 13.2, the election of species should not be proper. This is not found persuasive. The species of potassium channel lacks unity of invention because each of the potassium channels has a diverse structure and function. Thus, the species of potassium channel lacks a special technical feature with one another.

Finally, Applicant argues that enforcing the present restriction and species requirements would result in inefficiencies and unnecessary expenditures by the Applicant and the PTO. Applicant adds that the search and examination of each species would likely be co-extensive and would involve such interrelated art that the search and examination of the entire application can be made without burden on the Examiner. Applicant's arguments have been fully considered but are not found to be persuasive because Groups I-IV and the species of potassium channel require divergent literature searches. A search for the different inventions and species encompassed by the instant claims would not be coextensive with a search for the others. Searching all of the inventions and species in a single patent application would provide an undue search burden on the Examiner and the USPTO's resources because of the non-coextensive nature of these searches.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1, 3, and 5 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking

claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 24 July 2009.

Claim 2 is under consideration in the instant application as it reads upon the elected species of TWIK-1.

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Drawings

2. The drawings are objected to because Figures 1 and 3 do not comply with 37 C.F.R. § 1.84(U)(1), which states that partial views of a drawing which are intended to form one complete view, whether contained on one or several sheets, must be identified by the same number followed by a capital letter. Figures 1 and 3 of the instant application, for example, are presented on many separate panels. The multiple sheets of drawings which are labeled "Fig. 1" and "Fig. 3" in the instant specification should be renumbered "Figures 1A-1I" and "Figures 3A and 3C". Applicant is reminded that once the drawings are changed to meet the separate numbering requirement of 37 C.F.R. 1.84(U)(1), Applicant is required to file an amendment to change the Brief Description of the Drawings and the rest of the specification accordingly.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing

should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. The disclosure is objected to because of the following informalities:
 - 3a. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: “METHOD OF SCREENING FOR POTASSIUM CHANNEL MODULATORS”.

Appropriate correction is required.

Claim Objections

4. Claim 2 is objected to because of the following informalities:
 - 4a. Claim 2 uses the acronym “TWIK-1” without first defining what it represents in the independent claim. While the claims can reference acronyms, the material presented by the acronym must be clearly set forth at the first use of the acronym.

Appropriate correction is required.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
6. Claim 2 provides for the use of test compounds, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.
7. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 2 recites the broad recitation

cardiac dysrhythmias, and the claim also recites arrhythmias in parentheses which is the narrower statement of the range/limitation.

8. Claim 2 is indefinite because the elements recited in the claim do not constitute proper Markush groups. The claim is indefinite in the alternative use of “and/or” in line 3 because it is not clear what controls which of these limitations. See MPEP § 2173.05(h).

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claim 2 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by Lesage et al. (U.S. Patent 6,013,470).

Lesage et al. teach the nucleotide and amino acid sequences of the potassium channel, TWIK-1 (Figure 1B; SEQ ID NOs: 1, 2). Lesage et al. teach that cells expressing TWIK-1 channels are useful for the screening of substances capable of modulating the activity of the TWIK-1 channel (column 8, lines 17-22). Lesage et al. disclose that the screening is carried out by bringing into contact variable amounts of a substance to be tested with the cells expressing TWIK-1, then measuring, by any suitable means, the possible effects of said substance on the currents of the potassium channel (column 8, lines 22-28). Lesage et al. teach that the screening procedure makes it possible to identify drugs that are useful in the treatment of diseases of the heart, such as heart arrhythmias and vascular diseases (column 8, lines 29-37).

Conclusion

No claims are allowable.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Prior art that teaches TWIK-1 and screening methods using TWIK-1

Honore et al. WO9945108

Honore et al. U.S. Patent 6,942,979

Golz et al. WO 2005/054864

Bednarik, D. US 20060275770

Lesage et al. Am J Physiol Renal Physiol 279(5): F793-F801, 2000.

Lesage et al. EMBO J 15: 1004-1001, 1996.

Lesage et al. FEBS Lett 402: 28-32, 1997.

Gardener et al. Brit J Pharmacol 142(1): 192-202, 2004.

Ellinghaus et al. J Thoracic Cardiovasc Surg 129(6): 1383-1390, 2006.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (571) 272-0881. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BEB
Art Unit 1647
24 September 2009

/Bridget E Bunner/
Primary Examiner, Art Unit 1647